



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

Element Materials Technology Daleville, LLC dba Element Warsaw

**909 Executive Drive
Warsaw, IN 46580**

has been assessed by ANAB and meets the requirements of international standard

ISO/IEC 17025:2005

and the

AOAC International Guidelines for Laboratories performing Microbiological and Chemical Analysis of Food and Pharmaceuticals

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of activities to which this accreditation applies

L2228

Certificate Number

ANAB Approval

Certificate Valid Through: 02/20/2022
Version No. 002 Issued: 02/07/2019



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



ANSI National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

and

AOAC INTERNATIONAL GUIDELINES FOR LABORATORIES PERFORMING MICROBIOLOGICAL AND CHEMICAL ANALYSIS OF FOOD AND PHARMACEUTICALS

Element Materials Technology Daleville, LLC dba Element Warsaw

909 Executive Drive Warsaw, IN 46580

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TESTING

Valid to: February 20, 2022

Certificate Number: L2228

Microbiology

Table with 4 columns: Specific Tests and/or Properties Measured, Specification, Standard, Method, or Test Technique, Items, Materials or Product Tested, Key Equipment or Technology. Rows include E. Coli, Total Bacterial Count, Total Coliform, Yeast and Mold, and Heterotrophic Plate Count.





Microbiology

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Staphylococcus Aureus	AOAC 2003.07; AOAC 2003.08; AOAC 2003.11	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Limulus Amebocyte Lysate (LAL)	USP <85>; USP <161>; ANSI/AAMI ST72	Aqueous, Medical Devices	Plate Reader, Clean Room
E. Coli 0157:H7	AOAC 2000.14; AOAC RI 021501	Food Products, Ingredients, Swabs	Incubator, ELISA, RT-PCR
Salmonella Enteritidis (PCR)	SOP No. 7011	Environmental Swabs and Shell Eggs	Incubator, RT-PCR
Salmonella Enteritidis (Reveal)	AOAC RI111001	Environmental Swabs and Shell Eggs	Incubator, ELISA
Salmonella Species (PCR)	AOAC RI 120301 AOAC RI 051303	Food Products, Ingredients, Swabs	Incubator, RT-PCR
Listeria Monocytogenes (PCR)	AOAC RI 070401 AOAC RI 071304	Food Products, Ingredients, Swabs	Incubator, RT-PCR
Listeria Species (PCR)	AOAC RI 070401 AOAC RI 061302	Food Products, Ingredients, Swabs	Incubator, RT-PCR
Enterobacteriaceae	AOAC 2003.01	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Bioburden	ISO 11737-1	Medical Device	Incubator, Agar Plates
Total Aerobic Microbial Count (TAMC); Total Yeast & Mold Count (TYMC) - Microbial Limits Test	USP <61>; USP <62>	Pharmaceuticals, Ingredients	Incubator, Agar Plates
Escherichia coli Salmonella Staphylococcus aureus Pseudomonas aeruginosa Clostridia Candida albicans	USP <62>	Pharmaceuticals, Ingredients, Water	Incubator, Agar Plates
Cytotoxicity	ISO 10993-5; USP<87>	Aqueous, Ingredients, Materials, Medical Devices	CO ² Incubator, Microscope



Chemistry

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Calcium by EDTA	AOAC 983.19	Meat	Titration
pH	SM 4500 HB; AOAC 981.12; USP <791>	Water, Aqueous, Food Samples	Ion Meter
Water Activity	AOAC 978.18	Food Products, Ingredients	Water Activity Meter
Moisture (Loss on Drying)	AOAC 925.10; AOAC 926.08; AOAC 950.46; AOAC 930.15	Food Products, Ingredients	Air Oven, Balance
Ash	AOAC 923.03	Food Products, Ingredients	LECO
Protein	AOAC 992.15; AOAC 990.03	Food Products, Ingredients	LECO
Fat	AOCS Am 5-04	Food Products, Ingredients	Ankom
Fiber	AOCS Ba 6a-05	Food Products, Ingredients	Ankom
TOC	USP <643>; SM 5310C	Water, Swabs, Medical Devices	GE
Conductivity	USP <645>	Water	GE

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. L2228.

Vice President